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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/171,607	11/04/1998	WOLF-GEORG FORSSMANN	P63132USO	8253

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EXAMINER
DECLOUX, AMY M

ART UNIT	PAPER NUMBER
1644	23

DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/171,607	Applicant(s) FORSSMANN ET AL.	
	Examiner Amy M. DeCloux	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet* .

Continuation of Attachment(s) 6). Other: Notice to Comply with Requirements for disclosures with sequences.

DETAILED ACTION

Election/Restrictions

Applicant's response filed 11-22-02 (Paper No. 22) to the species requirement of newly added claims mailed 10-22-02 (Paper No.1) is acknowledged. In view of Applicant's remarks and upon reconsideration, the species requirement has been withdrawn.

Claims 43-62 are pending.

Priority

In view of Applicant's remarks filed 11-22-02 (Paper No. 22), priority is granted under 35USC119 to DE19615710.2, filed 4-24-1996.

In view of Applicant's newly added claims and cancellation of originally pending claims, the outstanding rejections have been withdrawn. However, a new grounds of rejection has been applied in this non-final office action.

Specification

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Specifically sequences without SEQ ID NO: tags are disclosed on pages 3 and 10 of the specification. Applicant is reminded of the sequence rules which require a submission for all sequences of more than 9 nucleotides or 3 amino acids (see 37 C.F.R. 1.821-1.825) and is also requested to carefully review the submitted specification for any and all sequences which require compliance with the rules.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 43-44 and 50 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A peptide having the amino acid sequence of SEQ ID NO:1 as recited in claims 43-44 would read on a peptide found in nature and constitutes non-statutory subject matter. Applicant's own specification describes its purification from human hemofiltrate (page 11 of the specification). An antibody reactive with said peptide as recited in claim 50 would read on an antibody found in an animal and constitutes non-statutory subject matter. It is noted that the method of making said antibody dooes not carry patentable weight in a product claim. Therefore the instant claims read upon a peptide and an antibody found in an intact organism, which is a naturally occurring product of nature and thus constitutes non-statutory subject matter. Amending the claims by modifying said peptide and said antibody with the adjective purified or isolated is one way to overcome this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 43, 45, 48-51, 56 and 62 are rejected under 35 U.S.C. 102(e) as being anticipated by Olsen et al. (US Patent 5,643,783).

'783 teaches a peptide having the sequence of SEQ ID NO:1 as recited in instant claim 43, (note open language of the instant claims) (see entire patent, especially column 2, lines 1-2 of '783). '783 teaches a process of preparing said peptide through prokaryotic or eukaryotic expression (see entire patent, especially column 12, lines 1-30), as recited in instant claim 45. '783 teaches a medicant comprising the peptide comprising SEQ ID NO:1 (see entire patent, especially column 12, lines 46-60), as recited in instant claims 48-49. '783 teaches antibodies obtainable by immunizing an animal with a peptide having the sequence of SEQ ID NO:1, or by hybridoma technology as recited in instant claim 50 (see entire patent, especially column 12, lines 34-44). '783 teaches a method for the treatment of patients by the administration of a peptide comprising SEQ ID NO:1, HF_COLL-18/514cf as recited in instant claim 51, (see entire patent, especially column 12, lines 30-67). '783 teaches a method of administering said peptide for the treatment of diseases involving the integument, (see entire patent, especially column 12, lines 46-60). '783 teaches a diagnostic agent comprising a peptide comprising SEQ ID NO:1, HF_COLL-18/514cf, as recited in instant claim 62, (see entire patent, especially column 12, lines 30-44). Therefore, the referenced teachings anticipate the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 51-62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to a method for treatment of patients comprising the administration of HF-COLL-18/514cf or administration of an antagonist of HF-COLL-18/514cf, and encompasses treatments for diseases in connection with capillary proliferations, carcinoses, cardiovascular and nervous system diseases, diseases involving the integument and the sense organs, disorders in inflammatory processes, disturbed inflammatory reactions, proliferation and maturation disorders of the blood forming system, systemic diseases, tumor and vascular diseases, and acute diseases in intensive care, and an agent for the diagnosis of diseases.

The instant specification describes one in vitro assay in which bovine endothelial cells which had been cultured with BFGF for 24 hours, incubated for 30 minutes with HF-COLL-18/514cf followed by the addition of BFGF, showed decreased endothelial cell proliferation after 72 hours in culture when compared to similarly treated cells not incubated with HF-COLL-18/514cf. The instant specification discloses no actual treatments with the claimed protein. The closest prior art, US Patent 5,643,783 which teaches a peptide comprising the sequence of SEQ ID NO:1 HF-COLL-18/514cf, also does not exemplify treatment with a peptide having the sequence of SEQ ID NO:1.

In view of the unpredictability of the effect of said peptide or antagonist thereof, in the treatment and/or diagnosis of the claimed diseases and disorders, it would require undue experimentation for one of skill to make and use a medicant and/or diagnostic agent for the purpose of treating and/or diagnosing the recited diseases and disorders, without further guidance and direction from the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 44-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 44-62 are indefinite in the recitation of the phrase "its amidated, acetylated, phosphorylated, or glycosylated derivative" because it is not clear if said derivative must comprise and/or consist of SEQ ID NO:1 which is its amidated, acetylated,

phosphorylated, or glycosylated, or if said derivative can be any derivative of SEQ ID NO:1, which is its amidated, acetylated, phosphorylated, or glycosylated.

B) Claims 44-62 are indefinite in the recitation of "a peptide having the amino acid sequence ... SEQ ID NO:1" because it is not clear if closed or open language is intended.

Conclusion

No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 872-9306 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy M. DeCloux 2-23-03

Amy DeCloux, Ph.D.
Patent Examiner,
Group 1640
February 23, 2003